

**This Page Is Inserted by IFW Operations
and is not a part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- **BLACK BORDERS**
- **TEXT CUT OFF AT TOP, BOTTOM OR SIDES**
- **FADED TEXT**
- **ILLEGIBLE TEXT**
- **SKEWED/SLANTED IMAGES**
- **COLORED PHOTOS**
- **BLACK OR VERY BLACK AND WHITE DARK PHOTOS**
- **GRAY SCALE DOCUMENTS**

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

DEVICE, METHOD, AND USE AT A MEDICAL IMPLANTTechnical field of the invention

The present invention relates generally to the field of medical implants. More specifically, the present invention relates to a sealing structure in a medical implant and a method of preserving the function during storage of self-sealing access slits in a sealing structure mounted in a medical implant.

Background of the invention

Medical implants, heart stimulators, cardiac pacemakers, defibrillators, etc., are used for generating electric pulses, and for delivering these pulses to a heart. The pulses generated by a pulse generator within the implant are transmitted to the heart by at least one insulated electric conductor connected to the implant, which at the opposite end is provided with an electrode affixed to the conductor, generally an endocardial electrode. The conductor and the electrode are comprised in a cardiac lead.

The endocardial electrode is in direct contact with the tissue within the heart, and may be anchored to the heart in order to prevent it from being dislodged due to the motion of the heart during heartbeats. Furthermore, the tissue of the heart grows around the electrode tip, which increases the fixation of the electrode to the tissue.

Medical implants run on batteries, which means that an implant must be replaced when its batteries are running low. To facilitate removal of the implanted pulse generator without having to remove the lead, medical implants are provided with a terminal block including a set or fixing screw for readily connecting and disconnecting an endocardial lead from the implant. Generally, such a fixing screw and terminal block are shielded from body

fluids, while access to the fixing screw is allowed through the shield. The shielding protects the fixing screw and the terminal block from electric leakage and from the accumulation of solid body materials that could 5 interfere with the manipulation of the fixing screw when disconnecting the lead from the implant.

US-A-4,479,489 discloses such a shielding in the form of a mechanically self-sealing plug or structure for sealing the electrical terminal block of a cardiac pacing 10 device from contact with body fluids while allowing access to a set screw of the terminal block when the plug is in place. The plug (28) is formed of an elastomeric material, inserted into a recess (24) of a medical implant, and secured within the recess with an adhesive material 15 in addition to a compression fit. The plug includes a slit portion (30), cut out of the plug at the time of manufacturing, which allows for insertion of a tool into the slit for engagement with a set screw (20) of a terminal block (18). Upon removal of the tool, the 20 slit (30) closes, thereby effective sealing out body fluids from the set screw and the electrical terminal block.

When a medical implant is stored for a longer period prior to the implantation into a patient, the access slit(s) of a self-sealing structure, such as described in 25 said US patent, tends to net together. The opposite surfaces of the access slit sometimes are lubricated with a silicone-based lubricant, which further enhances the netting process.

It is therefore an object of the present invention 30 to provide for preservation of a self-sealing access slit in a sealing structure mounted in a medical implant.

Summary of the invention

The object is achieved in accordance with the present invention by providing a sealing structure and a 35 method having the features defined in the independent

claims. Preferred embodiments are defined in the dependent claims.

The invention preferably is based on the use of an insert for preserving a self-sealing slit during storage.

5

Preferably, use is made of an insert that at one end, the distal end, is provided with protrusions, e.g. in the shape of tongues or leaves, for insertion into corresponding self-sealing access slits in a sealing plug 10 of a medical implant. Following the manufacture and assembly of the medical implant, including the mounting of the sealing structure or plug, and prior to the packaging of the medical implant, each protrusion of the insert is inserted into a corresponding self-sealing slit in the 15 plug. The insert is then stored together with the medical implant in a storing package with the protrusions of the insert remaining within the corresponding self-sealing slits throughout the period of storing the medical implant prior to implantation. Thereby, the opposite 20 surfaces of the self-sealing slit is kept apart, or at least the contact area between the surfaces is minimised, such that the netting together of the slit is greatly reduced or eliminated.

The insert is preferably made from a flexible polymer material, such as polyethylene, polytetrafluoroethylene (Teflon[®]), polyethyleneterephthalate-G (PETG). However, other polymer materials are contemplated, provided that the chosen material has a flexibility that is sufficient for the protrusions not to damage the soft sealing 30 plug when inserting the protrusions into the slit. Other materials, such as metals, can of course also be conceivable if the protrusion has a tip portion with a sufficiently blunt or rounded shape, such that the slit of the sealing plug will not be damaged.

35 The shape of the protrusions, or rather the end portion or tip of each protrusion, are formed such that insertion of the protrusion into the corresponding slit is

facilitated, while the risk of damaging the slit during insertion is reduced. Therefore, the ideal tip shape depends on the chosen material. However, for a flexible plastic material, the tip of the protrusion is preferably 5 formed in a cone, a double-bevel or a single-bevel configuration, which facilitates the insertion of the protrusions into the corresponding slits. Other configurations, such as a square or a rounded configuration, are also conceivable for reducing the risk of damaging the 10 plug.

The insert is preferably formed from a thin strip that is cut out at one end for forming the protrusions. The insert can also be formed by moulding.

Since the number of cardiac leads used can vary depending 15 on the implant used for a particular patient, the number of connections in a terminal block, the number of fixing screws, and the number of access slits vary accordingly. Generally, the medical implant is connected to one or two leads, but three or four leads are also possible. Furthermore, each connection can be provided with 20 one or more fixing screws, each fixing screw being accessed through a separate access slit. Therefore, the insert is provided with a chosen number of protrusions depending on the particular medical implant for which it is intended. Furthermore, the position(s) of the protrusion(s) is naturally adapted to the configuration and 25 positioning of the access slit(s) on the medical implant.

According to an embodiment of the present invention, the insert is preferably given a configuration at its 30 proximal end that facilitates the removal of the insert from the medical implant, e.g. of the protrusion(s) from the corresponding access slit(s). Preferably, the proximal end of the insert is formed as a handle, or the like, that can be readily manipulated by the physician for removal 35 of the insert from the medical implant prior to implantation of the implant.

When storing a medical implant, the implant is generally enclosed in a storing package having a lower portion or tray, and an upper portion or cover. According to an advantageous alternative embodiment of the present invention, the insert, provided with the protrusions for insertion into the corresponding slits of the sealing plug, is connected to the bottom of the tray. Thereby, upon removal of the implant from the storing package prior to implantation, the insert will be automatically withdrawn from the implant. Thus, the insert can not interfere with any manipulation of the implant after removal of the implant from the storage package.

According to this embodiment, the insert is preferably made of the same material as the storage tray for facilitating the adherence of the insert to the tray, e.g. by fusing the parts together. As an alternative, the insert can be formed integral with the storage tray, e.g. by moulding.

Preferably, the insert has an elongated shape that is folded into the storage tray. Thereby, the insert can be extended from the tray, as the bellows of an accordion, for providing the possibility of inserting the protrusions into the slits at a small distance away from the tray, thus facilitating said insertion. The insert is preferably folded in the storage tray such that the insert at its most proximal end is joined with the storage tray at a position directly underneath the access slit(s), when the implant is positioned in the tray. Thus, when the implant is pulled away from the tray, the action of pulling the insert out of the slits is facilitated and the risk of damaging the slits when removing the insert is considerably reduced.

As an alternative embodiment, the slits of the sealing plug can be produced with the aid of the protrusions of the insert, e.g. by moulding the sealing plug about the protrusion.

Further details and aspects of the invention will become apparent from the following detailed description of embodiments of the invention, reference being made to the accompanying drawings.

5

Brief description of the drawings

Fig. 1 is a side elevational view of an insert according to an embodiment of the invention, a medical implant, and a storage tray, when the insert is inserted 10 into the medical implant.

Fig. 2 is an enlarged cross-sectional view of the insert, medical implant, and storage tray according to the embodiment shown in Fig. 1.

Figs 3a and 3b are side and top elevational views, 15 respectively, of an insert according to an embodiment of the invention shown in a folded configuration.

Fig. 4 is a top elevational view of the insert shown in Figs 3a and 3b, shown in an extended configuration.

Fig. 5 is a side elevational view of an insert according to an alternative embodiment of the invention. 20

Detailed description of preferred embodiments

With reference to Figs 1 and 2, there is shown a medical implant in the form of a pacemaker 1 when positioned on a storage tray 30. The pacemaker 1 comprises at 25 one end a connector or header 2 containing a connector block 3 having a lumen or receptacle 4 for receiving the terminal pin of a cardiac lead (not shown). The opening of the receptacle 4 through which the terminal pin is inserted is sealed from the pacemaker surroundings, when the terminal pin is located within the receptacle 4, 30 through sealing means (not shown) provided on the terminal pin and in the receptacle 4.

The connector block 3 is provided with a fixing screw 5 for securing the terminal pin in the receptacle 4 and for ensuring a stable electrical connection between the cardiac lead and the battery and circuitry of the 35

pacemaker 1. The fixing screw 5 is preferably a socket screw that can be accessed by a suitable tool through an opening provided in the header 2. For sealing the opening the header is provided with a flexible plug 20, which 5 preferably is made of silicone rubber. For enabling access to the fixing screw 5, the plug 20 is provided with an access slit 21, as described in the US patent above, through which a tool can be inserted for manipulation of the fixing screw 5. Due to radially directed compression 10 forces exerted on the plug 20 by the surrounding walls of the opening in the header 2, the access slit 21 is self-sealing, whereby the plug 20 tightly seals the interior of the terminal block 3 from the pacemaker surroundings. The opposite surfaces of the access slit 21 sometimes is 15 lubricated with a silicone-based lubricant for facilitating insertion of the tool through the access slit 21.

For illustrative purposes, Figs 1 and 2 show a pacemaker 1 with a single receptacle 4 for receiving a single cardiac lead that is secured by a single fixing screw 5. 20 However, several cardiac leads can be connected to a single pacemaker. Furthermore, the terminal pin of each cardiac lead can be secured with more than one fixing screw. Therefore, the total number of access slits in a pacemaker can vary in accordance with the total number of 25 fixing screws to be accessed.

When storing a pacemaker for a longer period of time, the access slit 21 of the plug 20 tends to net together, as mentioned above. According to the invention, an insert 10 is provided for insertion into the access 30 slits 21 during storage, thereby preserving the function of the access slits 21 during extensive storage. The insert 10 preferably has a thin, elongated body portion 12 and is at its most distal end provided with protrusions 11, which are provided essentially perpendicular to the 35 elongated body portion 12. The number of protrusions 11 correspond to the number of access slits 21 of the pacemaker 1, and the protrusions 11 are arranged in a con-

figuration corresponding to the configuration of the access slits 21. The insert is preferably formed from a flexible plastic material in order for the protrusions not to damage the plugs 20 or the access slits 21 when 5 inserting the protrusions 11 into the access slits 21. The tip portion of the protrusions 11 have an essentially rounded shape, but other alternative shapes are contemplated.

In Fig. 1, the insert 10 is shown as a separate element 10 that is not attached to the storage tray 30. However, according to embodiments of the invention, the insert 10 can be connected to the tray 30, e.g. by forming an integral part thereof or being attached through an adhesive or by fusing. As is shown schematically in Fig. 1, 15 for purposes that will be described below, the elongated body portion 12 of the insert 10 is preferably folded.

Figs 3a and 3b show side and top elevational views, respectively, of the insert 10 according to the invention shown in a folded configuration. The folds are provided 20 at the proximal end of the insert 10 and of the elongated body portion 12 for enabling the insert 10 to fit into a storage tray 30 and for facilitating the removal of the insert 10 from the pacemaker 1. Furthermore, if connected to the storage tray 30, the insert 10 can be extended 25 from the tray 30, for providing the possibility of inserting the protrusions 11 into the slits 21 at a small distance away from the tray 30, which facilitates the insertion. The preferred number of folds vary in accordance 30 with the shape of the storage tray 30 and the method of manipulating the insert 10, i.e. if the insert 10 is integral with the tray 30 or if it is provided with a handle or the like.

Fig. 4 show an insert 10 according to an embodiment 35 of the invention wherein the elongated body portion 12 is provided with a hole 14, which is arranged for facilitating the removal of the insert 10 from the pacemaker 1 by simply pulling the insert 10 out of the pacemaker 1.

Thereby, the elongated body portion 12 functions as a handle. The insert 10 according to the embodiment shown in Fig. 4 is preferably formed as a single element, which is not attached to the storage tray 30. Said insert 10 5 can be folded or be kept unfolded depending on the configuration of the storage tray.

In Fig. 5 there is shown an alternative embodiment of an insert 10' according to the present invention. The insert 10' is provided with protrusions 11 in the same 10 manner and with the same function as described above. The insert 10' is further provided with an elongated body portion 12', which is folded once such that the elongated body portion 12' is divided into an upper portion and a lower portion, which generally has the same extension in 15 the longitudinal direction. Thereby, the elongated body portion 12' terminates at its proximal end at an area 13 located essentially straight underneath the protrusions 11 when the insert 10' is folded and the insert 10' and the pacemaker 1 are positioned for storing.

20 The insert 10' according to this embodiment is connected to a storage tray 30, either being integral with or attached to the storage tray 30. Thus, when removing the pacemaker 1 from the storage tray 30 prior to implantation of the pacemaker 1, the insert 10' will unfold and 25 will obtain a generally linear extension in the longitudinal direction of the protrusions 11 and the access slits 21. Thereby, the protrusions 11 are pulled out of the access slits 21 in a straight direction, thus eliminating turning of the protrusions 11 relative the access 30 slits 21 during the removal of the insert 10'.

Although the present invention has been described by way of exemplifying embodiments with reference to the accompanying drawings, as apparent to those skilled in the art various changes and modifications are possible without departing from the scope of the invention, which is 35 defined in the accompanying claims.

CLAIMS

1. A sealing structure (20) for a medical implant (1), said sealing structure being provided with at least one self-sealing access slit (21), **characterised in that** 5 each of said slit(s) (21) is provided with means (10, 10', 11) for minimising the contact area of the opposite surfaces of the slit(s) (21).

2. The sealing structure (20) according to claim 1, 10 wherein said means for minimising the contact area is a removable insert (10, 10'), said insert (10, 10') being provided with at least one protrusion (11) located in one of said slit(s) (21).

15 3. The sealing structure (20) according to claim 2, wherein said insert (10) is attachable to a storing package for storing of said medical implant (1).

4. A method for preserving the function during storage of self-sealing access slits (21) in a sealing structure (20) mounted in a medical implant (1), said sealing structure (20) being provided with at least one such slit (21), **characterised by the steps of:** 20

retaining a protrusion (11) of an insert (10, 10') 25 within each of said at least one slit (21) during storage of the medical implant (1), thereby preserving the function of said slit(s) (21); and

removing said protrusion(s) (11) from said slit(s) 30 (21) prior to implantation of the medical implant (1), thereby allowing access of a tool through said slit(s) (21).

5. The method according to claim 7, comprising the steps of

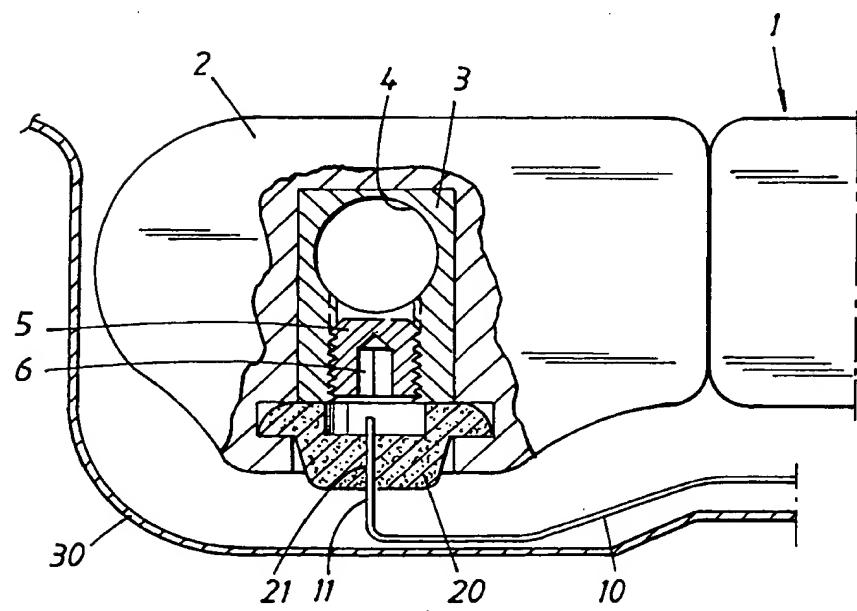
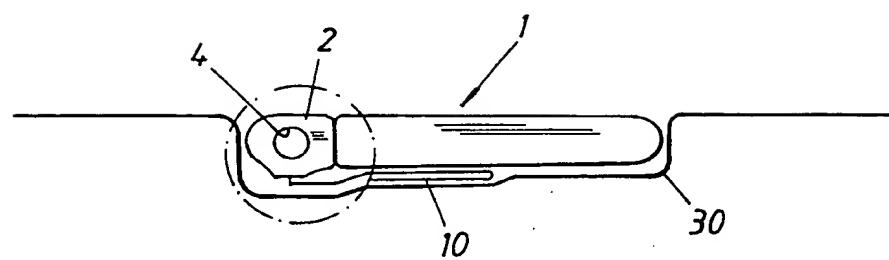
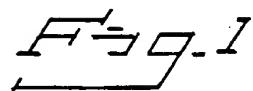
11

providing a storing package with said insert (10,
10');

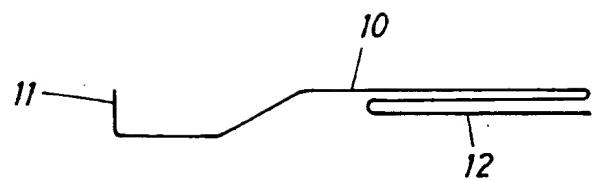
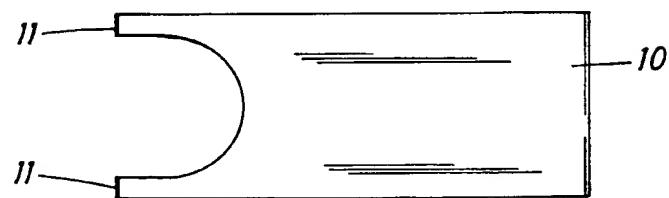
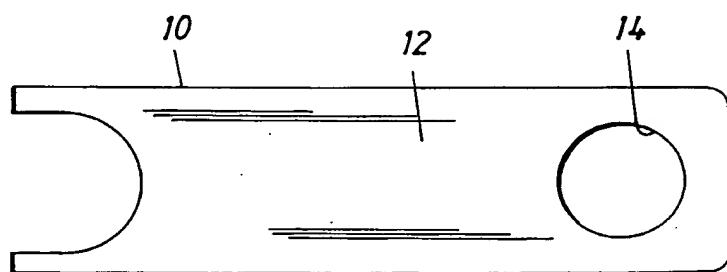
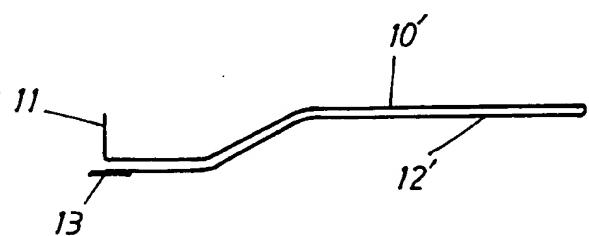
storing the medical implant (1) in said storing
package; and

5 removing the medical implant (1) from said storing
package prior to implantation, thereby also removing the
protrusion(s) (11) from the slit(s) (21).

1 / 2



2 / 2

Fig. 3aFig. 3bFig. 4Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01851

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/375

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4932409 A (J.HIRSCHBERG), 12 June 1990 (12.06.90), abstract --	1-5
D,A	US 4479489 A (C.TUCCI), 30 October 1984 (30.10.84), abstract -----	1-5

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
5 December 2000

Date of mailing of the international search report
12-12-2000

Name and mailing address of the ISA/
Swedish Patent Office
Box 5055, S-102 42 STOCKHOLM
Facsimile No. + 46 8 666 02 86

Authorized officer
Nikolaj Hautaviita /itw
Telephone No. + 46 8 782 25 00

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/SE 00/01851

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 4932409 A	12/06/90	DE 58905995 D	00/00/00	EP 0342392 A;B 23/11/89
US 4479489 A	30/10/84	NONE		